IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD., Plaintiff, v. SAREPTA THERAPEUTICS, INC., Defendant.	C.A. No. 21-1015 (JLH) [redacted]
SAREPTA THERAPEUTICS, INC. and THE UNIVERSITY OF WESTERN AUSTRALIA, Defendant/Counter-Plaintiffs, v. NIPPON SHINYAKU CO., LTD. and NS PHARMA, INC. Plaintiff/Counter-Defendants.	**PUBLIC VERSION** **Confidential Version Filed: January 12, 2024** **Public Version Filed: January 19, 2024**

SAREPTA THERAPEUTICS, INC. AND THE UNIVERSITY OF WESTERN AUSTRALIA'S OPPOSITION TO PLAINTIFF/COUNTER-DEFENDANTS' *DAUBERT* MOTIONS

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TABLE OF ABBREVIATIONS

Abbreviation	Description
'851 Patent	U.S. Patent No. 9,994,851
'590 Patent	U.S. Patent No. 10,227,590
'827 Patent	U.S. Patent No. 10,266,827
'361 Patent	U.S. Patent No. 9,708,361
'092 Patent	U.S. Patent No. 10,385,092
'461 Patent	U.S. Patent No. 10,407,461
'106 Patent	U.S. Patent No. 10,487,106
'741 Patent	U.S. Patent No. 10,647,741
'217 Patent	U.S. Patent No. 10,662,217
'322 Patent	U.S. Patent No. 10,683,322
ASO	Antisense oligonucleotide
Bold and Italic	Emphasis added unless indicated otherwise
Br-1	NS's Memorandum of Law in Support of Its *Daubert* Motion to Exclude Testimony and Opinions of Steven F. Dowdy, Ph.D. (D.I. 421)
Br-2	NS's Memorandum of Law in Support of Its *Daubert* Motion to Exclude Testimony and Opinions of Andrew Hirshfeld (D.I. 424)
DMD	Duchenne muscular dystrophy
Ex. ____	Exhibit ____[1]
NS	Plaintiff/Counter-Defendants Nippon Shinyaku Co., Ltd. and NS Pharma, Inc.
NS Patents	U.S. Patent Nos. 9,708,361; 10,385,092; 10,407,461; 10,487,106; 10,647,741; 10,662,217; 10,683,322
PMO	Phosphorodiamidate morpholino oligomer
POSA	Person of ordinary skill in the art
Sarepta	Defendant/Counter-Plaintiff Sarepta Therapeutics, Inc.
UWA	Counter-Plaintiff The University of Western Australia
Wilton Patents	U.S. Patent Nos. 9,994,851; 10,227,590; and 10,266,827

[1] Refers to Exhibits to the accompanying Declaration of Megan E. Dellinger in Support of Sarepta Therapeutics, Inc. and The University of Western Australia's Oppositions to Plaintiff/Counter-Defendants' Motions for Summary Judgment and Motions to Exclude Certain Opinions and Testimony of Steven F. Dowdy, Ph.D. and Andrew Hirshfeld.

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I. INTRODUCTION

Sarepta and UWA respectfully request that the Court deny NS's *Daubert* motions to exclude: (1) testimony and opinions of Steven F. Dowdy, Ph.D. and (2) testimony and opinions of Andrew Hirshfeld.

II. OPPOSITION TO NS'S *DAUBERT* MOTION #1 (STEVEN F. DOWDY, PH.D.)

A. Summary of Argument

Sarepta's expert, Dr. Steven Dowdy, has over forty years of experience relevant to the antisense oligonucleotide ("ASO") technology at issue in this case. His research focuses on targeted delivery of ASOs and other nucleic acid-based therapeutics. D.I. 427-1, ¶¶4-10 and Appx. A. Dr. Dowdy's opinions regarding the technical issues underlying: (1) the written description and enablement of the Wilton Patents, (2) the materiality and intent prongs of inequitable conduct for the NS Patents, and (3) the *inter partes* review petitions and accompanying expert declarations submitted by Sarepta for the same claims of the NS Patents asserted in this case will assist the trier of fact in understanding the parties' positions on these issues. NS's arguments in its *Daubert* motion boil down to a disagreement with Dr. Dowdy's opinions (which is appropriately addressed through cross-examination), not with the reliability of those opinions.

B. Dr. Dowdy Should Be Permitted to Testify Regarding the Technical Aspects of Written Description and Enablement for the Wilton Patents

There is no dispute regarding Dr. Dowdy's extensive qualifications and their relevance to this case. NS nevertheless seeks to preclude Dr. Dowdy from testifying about written description and enablement, arguing he should not be allowed to rely on the plain and ordinary meaning of the term "antisense" oligonucleotide. NS is wrong. During *Markman,* the Court did not construe this term because ***NS insisted*** it was not in dispute. Consequently, the term must be given its plain and ordinary meaning—a meaning both sides' experts agree on. Dr. Dowdy's testimony on the plain

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and ordinary meaning of "antisense" oligonucleotide is all the more necessary here, in view of NS's extreme position that the term can be ***entirely ignored*** for purposes of its invalidity arguments. *See Thorner v. Sony Comput. Ent. Am. LLC*, 669 F.3d 1362, 1367 (Fed. Cir. 2012) ("Our case law is clear, claim terms ***must be given their plain and ordinary meaning*** to one of skill in the art."); *Wasica Fin. GmbH v. Cont'l Auto. Sys., Inc.*, 853 F.3d 1272, 1288 n.10 (Fed. Cir. 2017) ("It is highly disfavored to construe terms in a way that renders them void, meaningless, or superfluous.").

NS's motion should be denied for the additional reason that, regardless of the "antisense" oligonucleotide term, Dr. Dowdy's opinions are relevant to the common structural features that a POSA would attribute to the claimed ASOs for analyzing written description and enablement.

1. Dr. Dowdy's Application of the Plain and Ordinary Meaning of "Antisense" Oligonucleotide Is Consistent with the *Markman* Ruling

The Wilton Patents claim an "antisense oligonucleotide . . . comprising a base sequence that is 100% complementary to consecutive bases of a target region of exon 53 of the human dystrophin pre-mRNA . . . ." (referred to during *Markman* as the Antisense Oligonucleotide Phrase). D.I. 417-1 (Ex. 1), claim 1. NS represented that the entire phrase need not be construed because the parties' dispute was limited to three terms: "base sequence," "target region," and "exon 53 of the human dystrophin pre-mRNA." *See, e.g.*, D.I. 166, 13-15; Ex. 1, 10:22-11:7. Based on these representations, the Court limited its construction to the three identified terms. *See* D.I. 248 at 6 (stating that "only those terms actually in dispute require a construction" and noting that "[t]he parties agree that the scope of the entirety of the Antisense Oligonucleotide Phrase is not in dispute").

NS's brief focuses on statements made by the parties during *Markman* regarding a ***different*** term: the "base sequence" term. As acknowledged by NS, however, the issue before the Court on

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that term was whether the "base sequence that is 100% complementary" to a target region referred to a portion or the entirety of the antisense oligonucleotide. *See e.g.*, Ex. 1, 28:24-29:2. The Court explained "that a 'base sequence' need only be included in the claimed [ASO] and that it need not, although it may, span the entirety of the [ASO]." D.I. 248 at 10-11. The Court did not address the portion of the antisense oligonucleotide ***outside*** of the "base sequence," or construe the term "antisense" oligonucleotide contrary to its plain and ordinary meaning. Indeed, the Court stated that "the patentee chose to recite 'a base sequence' as a separate claim term from 'antisense oligonucleotide,' which ***suggests that the two terms have distinct meanings***." *Id.* "Antisense" oligonucleotide must, therefore, be given its plain and ordinary meaning. *Thorner*, 669 F.3d at 1367 ("[C]laim terms ***must be given their plain and ordinary meaning***.").

Dr. Dowdy's application of the plain and ordinary meaning of "antisense" oligonucleotide is consistent with the Court's *Markman* ruling. Dr. Dowdy does ***not*** require that the claimed ASOs of the Wilton Patents be 100% complementary throughout their entirety. Rather, Dr. Dowdy applies the plain and ordinary meaning of the term to mean that, ***outside*** of the "base sequence" (which is 100% complementary), the ASO is highly complementary, if not 100% complementary to the exon 53 target region.[2] D.I. 427-2, ¶37; *see also infra* § II.B.2.

NS argues that Dr. Dowdy's application of the plain and ordinary meaning of "antisense" oligonucleotide is a "belated re-interpretation of the claims." Br-1 at 1. It is NS, not Sarepta, that belatedly reinterprets the claims, and it is NS's error to disregard the plain and ordinary meaning

[2] The cases cited by NS, *CAO Lighting, Inc. v. Gen. Elec. Co.*, No. 20-681-GBW, 2023 WL 1930354, at *6 (D. Del. Jan. 30, 2023), and *TwinStrand Biosciences, Inc. v. Guardant Health, Inc.*, No. 21-01126-GBW-SRF (D. Del. Dec. 4, 2023), D.I. 507 (Ex. 19) at 8 n.4, do not apply because here the Court expressly did not construe "antisense" oligonucleotide during *Markman* and Dr. Dowdy's application of the plain and ordinary meaning of this term is consistent with the Court's *Markman* ruling.

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of "antisense" after it argued the term did not need to be construed. *See Nuance Commc'ns, Inc. v. ABBYY USA Software House, Inc.*, 813 F.3d 1368, 1373 (Fed. Cir. 2016) (finding district court properly refused to reconsider construction where party "reversed course" and sought to switch constructions after district court accepted its prior proposal). Indeed, it was not until service of Dr. Hastings' Opening Expert Report on September 8, 2023, that it became clear that NS intended to disregard the claim term "antisense" oligonucleotide altogether. *See, e.g.*, D.I. 427-5, ¶46. Rather than applying the plain and ordinary meaning of "antisense" oligonucleotide, Dr. Hastings contends that outside of the "base sequence," the ASOs of the Wilton Patents can include ***up to 19*** random nucleotides that are ***not complementary*** to the target region. D.I. 427-5, ¶¶46-48; D.I. 427-2, ¶33; *see also* D.I. 401, ¶8 (Dr. Hastings "allow[s] for up to 19 mismatches").

2. Dr. Dowdy's Plain and Ordinary Meaning of "Antisense" Oligonucleotide, Agreed Upon by Dr. Hastings, Is Consistent with the Specification, the Prosecution History, and Real World Evidence

Based on the plain and ordinary meaning of the term "antisense" oligonucleotide, a POSA would have understood that the nucleotides in the claimed ASOs outside of the "base sequence" are highly complementary, if not 100% complementary, to the target region. D.I. 427-2, ¶¶35, 37, 40 (citing, *inter alia*, Ex. 14, 89 ("An ***antisense*** sequence is a DNA or RNA that is ***perfectly complementary*** to the target nucleotide sequence present in the cell."); Ex. 15, 99 (defining the term "***antisense*** RNA" to mean "[a]n ssRNA molecule that is ***complementary to a specific RNA transcript*** of a gene and capable of hybridizing with the specific RNA and blocking its function")). Indeed, the introduction of more than a single mismatch results in a reduction of the very high probability of binding compared to when a 100% complementary sequence is used. D.I. 427-2, ¶¶37, 40; Ex. 11, 16:4-17:6 ([redacted]); *id.*, 20:16-24 ([redacted]), 21:14-25 ([redacted]

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[redacted]), 30:2-12 ([redacted]). The specification and prosecution history support the plain and ordinary meaning of "antisense" oligonucleotide as highly complementary, if not 100% complementary. D.I. 427-2, ¶¶37-38; D.I. 417-1 (Ex. 1), 25:18-38; D.I. 428-6, SRPT-VYDS-0004782, -86.

Here, the experts ***agree*** regarding the plain and ordinary meaning. As the Court acknowledged in its *Markman* ruling, NS's expert Dr. Hastings has repeatedly used the term "antisense" oligonucleotide consistent with its plain and ordinary meaning of highly complementary. D.I. 248 at 17 n.4 (citing D.I. 171 (Ex. 48), 250 (antisense oligonucleotides "[redacted]"); *see also* Ex. 16, 172 (NS's expert Dr. Wood stating that antisense oligonucleotides are "[redacted]"). Dr. Hastings also acknowledged this plain and ordinary meaning of "antisense" oligonucleotide multiple times during her deposition. *E.g.*, Ex. 4, 240:11-241:17 (acknowledging that, as of June 2005, "antisense" oligonucleotides were "[redacted]"); *see also id.*, 72:21-73:9 ([redacted]).

3. Dr. Dowdy's Opinions Regarding Written Description and Enablement of the Wilton Patents Are Admissible Regardless of the "Antisense" Oligonucleotide Term

Even if the Court were to agree with NS that "antisense" should not be given patentable weight (i.e., that it could be disregarded in evaluating validity), Dr. Dowdy's written description and enablement opinions remain relevant under settled law. Indeed, Dr. Dowdy explains that "even if a high level of complementarity were not required by the claimed 'antisense oligonucleotide,' it

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is still a "common structural feature" of the claims. D.I. 427-2, 15 n.4, 160 n.37. *See Ajinomoto Co. v. Int'l Trade Comm'n*, 932 F.3d 1342, 1360 (Fed. Cir. 2019) ("written description does not require a perfect correspondence between the members of the genus and the asserted common structural feature" but instead a "more modes[t] . . . *correlation* between structure and function"). Dr. Dowdy explains that the specification teaches a POSA how various parameters (e.g., complementarity, length, chemical backbone, and target region) impact ASO function. D.I. 427-2, ¶¶38, 52, 57, 70, 74; Ex. 11, 186:2-187:10. Dr. Dowdy also explains that a POSA would have known how to efficiently make ASOs of the claims starting with 100% complementarity. D.I. 427-2, 160 n.37. Thus, even if the claim term "antisense" oligonucleotide is disregarded, Dr. Dowdy's opinions about the specification's teachings regarding "complementary" ASOs are legally relevant to both written description and the factual inquiries underlying enablement. *See also* §§ III.B.1, III.C.1.a of Sarepta's Opposition to NS's Motion #1 for Invalidity of the Wilton Patents.

Additionally, NS seeks without justification to exclude the ***entirety*** of Dr. Dowdy's written description and enablement opinions (D.I. 427-2, ¶¶27-290) even though many of his opinions are entirely independent of the "antisense" oligonucleotide term. Even the paragraphs that discuss "antisense" oligonucleotide also routinely address ***additional*** structural features of the claimed ASOs, such as, for example, the target region (*id.*, ¶¶42-44, 49-52), length (*id.*, ¶¶56-58, 61-66), chemical backbone and base sequence (*id.*, ¶¶56-58, 66) and the *Wands* factors, many of which are independent of "antisense" oligonucleotide (*id.*, ¶¶221-225, 227, 231-290). Similarly, the genus calculations NS specifically calls out (Br-1 at 3 n.2) are based not just on "antisense" oligonucleotide, but on additional structural features of the claims. *See* D.I. 427-2, ¶¶37 n.4, 74.

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C. NS's Motion to Exclude the Opinions of Dr. Dowdy Relating to Inequitable Conduct Should Be Denied

According to NS, Dr. Dowdy is not qualified to opine on inequitable conduct because he is not a patent law expert and lacks specialized training or experience with PTO examination procedures. Br-1 at 4-8. But the caselaw overwhelmingly demonstrates that in evaluating inequitable conduct, technical experts—not patent law experts as NS suggests—should opine on technical matters that are assessed from the perspective of a POSA. *See, e.g.*, *HVLPO2, LLC v. Oxygen Frog, LLC*, 949 F.3d 685, 688 (Fed. Cir. 2020) (for issues analyzed from the perspective of a POSA, a witness who is "not 'qualified as an expert by knowledge, skill, experience, training, or education' in the pertinent art . . . [cannot] assist the trier of fact to understand the evidence or determine a fact in issue"). NS has not cited a single case where a court prohibited a technical expert from opining on the technical aspects of inequitable conduct, and Sarepta is aware of none.[3]

Courts routinely permit technical experts to explain the relevance of technical information in the context of inequitable conduct. *See, e.g.*, *ART+COM Innovationpool GmbH v. Google Inc.*, 155 F. Supp. 3d 489, 503, 510-11 (D. Del. 2016) (permitting technical expert to testify on the accuracy of a declaration submitted to the PTO and relying on testimony of a technical expert relevant to intent); *Regeneron Pharms., Inc. v. Merus B.V.*, 144 F. Supp. 3d 530, 571-77 (S.D.N.Y. 2015), *aff'd* 864 F.3d 1343 (Fed. Cir. 2017) (considering technical expert testimony regarding the facts relevant to but-for materiality determination); *Medicines Co. v. Mylan Inc.*, No. 11–cv–1285, 2014 WL 1516599, at *5 (N.D. Ill. Apr. 17, 2014) (admitting a technical expert's testimony on "potential materiality").

[3] Sarepta's concurrently filed Opposition to NS's Motion for Partial Summary Judgment No. 5 regarding No Inequitable Conduct provides additional details regarding Sarepta's inequitable conduct theories.

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NS cites *J&M Industries, Inc. v. Raven Industries, Inc.*, 457 F. Supp. 3d. 1022, 1046-47 (D. Kan. 2020), alleging that a technical expert's materiality opinion was excluded. Br-1 at 5. But in *J&M Industries,* the court excluded a technical expert's opinion only as to "applicants' intent or specific state of mind in obtaining the [relevant patents]"—while allowing testimony on technical matters and their impact on validity. 457 F. Supp. 3d. at 1047, 1046 ("As a [POSA], Dr. Jones is qualified to offer opinions about technical aspects of the claimed invention and the prior art and how, in her opinion, it affects the validity of the patent."). The other case NS cites, *Lecat's Ventriloscope v. MT Tool & Mfg.*, 351 F. Supp. 3d 1100 (N.D. Ill. 2018), is also inapposite. There, the court concluded it was unnecessary for a ***patent law expert*** to testify regarding PTO procedures. *Id.* at 1115. The court did not exclude testimony from a technical expert like Dr. Dowdy. *See id.*

The facts relevant to the materiality prong of Sarepta's inequitable conduct theory are highly technical in nature and based on scientific data, known by named inventor Mr. Watanabe, that was not submitted to the PTO during prosecution. That information was inconsistent with technical arguments NS made to the PTO. D.I. 427-1, ¶¶636-676; Ex. 11, 158:15-159:1. The facts relevant to the intent prong of Sarepta's inequitable conduct theory are similarly technical in nature, as Sarepta alleges circumstantial evidence of intent based on a pattern of NS withholding contrary scientific data in multiple patent proceedings. D.I. 427-1, ¶¶679-735. Dr. Dowdy's testimony regarding those matters would be helpful for evaluating inequitable conduct.[4]

Moreover, contrary to NS's assertion (Br-1 at 6-8), Dr. Dowdy properly relies on the deposition testimony of Mr. Watanabe. That testimony reveals that [redacted]

[4] Dr. Dowdy does not speculate about what the examiner would have done or whether NS intentionally deceived the PTO. Ex. 11, 133:15-136:6, 142:18-25, 143:20-144:20, 154:14-23, 156:25-157:7; 160:23-161:12, 164:15-165:17 (explaining that he can't get into the examiner's head and clarifying that when he says "material to patentability," he is saying it from a scientific perspective and is not opining that the examiner would not have allowed the claims).

[redacted]; no more information is needed. [redacted] Ex. 9, 214:20-215:4. [redacted] (Ex. 10, 22:24-23:18, 24:9-25:15) and [redacted] (*id.*, 22:15-17).

D. NS's Motion to Preclude Dr. Dowdy from Relying on the IPRs and Corey Declarations in Support of His Obviousness Opinion Should Be Denied

In connection with Dr. Dowdy's obviousness opinions regarding the NS Patents, he cites to the *inter partes* review ("IPR") petitions submitted by Sarepta for the ***same claims*** of the NS Patents asserted in this case. Each of the seven IPR petitions was accompanied by a declaration from Dr. David Corey, President of the Oligonucleotide Therapeutic Society. D.I. 427-1, ¶619. The PTAB ***instituted*** IPR proceedings against all seven NS Patents, holding there was a reasonable likelihood all of the claims are unpatentable. Notably, NS does not seek to preclude Dr. Dowdy from relying on the IPRs to support his opinion that Sarepta has not willfully infringed the NS Patents. NS's own expert relied on the IPRs in support of her willfulness opinions. D.I. 427-4, ¶¶181, 339.

NS nevertheless seeks to preclude Dr. Dowdy's reliance on the IPRs for purpose of obviousness. As an initial matter, NS failed to meet and confer on this topic prior to filing its motion, which is alone grounds to deny its motion. *Bausch & Lomb Inc. v. SBH Holdings LLC*, C.A. No. 20-1463 (D. Del. May 12, 2023), D.I. 77 (Ex. 20) (denying motion to stay because defendant failed to meet and confer). Further, while NS argues potential jury confusion and prejudice, that is a topic properly considered in a motion *in limine*, which is an additional basis for

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denial. *E.g.*, *Robocast, Inc. v. Microsoft Corp*., C.A. No. 10-1055-RGA, 2014 WL 350062, at *3 n.5 (D. Del. Jan. 29, 2014) (declining to decide objections to testimony regarding prejudicial and irrelevant matters because "Microsoft's objections to testimony regarding prejudicial and irrelevant matters are properly dealt with at the *motion in limine* stage."); *Purdue Pharma LP v. Intellipharmaceutics Int'l, Inc*., C.A. No. 17-392-RGA (D. Del. Sept. 3, 2019), D.I. 212 (Ex. 21), at 2 ("Two of Defendants' arguments, about confusion and waste of time, are not *Daubert* arguments at all.").

This litigation involves the ***same*** patent claims, the ***same*** obviousness issues, and the ***same*** prior art considered by the PTO in the IPRs. *See Whereverty, Inc. v. Comcast Cable Commc'ns, LLC*, No. 2:18-CV-529-WJF-NPM, 2023 WL 2664200, at *6-7 (M.D. Fla. Mar. 28, 2023) (denying motion to exclude evidence of IPR proceedings based on overlap between prior art references and invalidity theories). Any potential confusion can be addressed by appropriate jury instruction on the applicable standards of proof in district court and IPRs. *See id.*; *Universal Elecs., Inc. v. Universal Remote Control, Inc.*, No. SACV 12-00329 AG (JPRx), 2014 WL 8096334, at *7 (C.D. Cal. Apr. 21, 2014). Tellingly, NS's expert Dr. Esau herself relies on them for willfulness. D.I. 427-4, ¶¶181, 339. That is, NS seeks to rely on the IPR proceedings for the points that are purportedly helpful for it while simultaneously preventing Sarepta from referencing the same proceedings. And in evaluating validity, NS's other experts, including Dr. Hastings, rely on a PTO proceeding involving ***patents not in suit***, as well as a related expert declaration. *See, e.g.*, D.I. 427-5, ¶¶44, 143. NS's *Daubert* motion to exclude the testimony and opinions of Dr. Dowdy should be denied in its entirety.

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III. OPPOSITION TO NS'S *DAUBERT* MOTION #2 (ANDREW HIRSHFELD)

A. Summary of Argument

NS moves to exclude specific paragraphs of Mr. Hirshfeld's analysis because they purportedly state "legal opinions . . . on issues of patentability, inequitable conduct, and the duty of candor."[5] *See* Br-2 at 1. NS omits that ***its own legal expert***, Dr. Kamholz, opined on these issues first, which prompted Mr. Hirshfeld's rebuttal. As explained in Sarepta's *Daubert* motion (and as NS's cited authority confirms here), Dr. Kamholz's opinions are inadmissible under blackletter law. *See* D.I. 395 at 2-8. If the Court grants Sarepta's *Daubert* motion, there will be no need for Mr. Hirshfeld to respond to these opinions, and Sarepta will withdraw the paragraphs NS challenges. But if the Court permits Dr. Kamholz to bring his improper opinions to trial, Mr. Hirshfeld should be permitted to rebut them.

B. Argument

The parties agree "legal opinions" from any legal expert are improper. *See* Br-2 at 2-3; *see also AstraZeneca UK Ltd. v. Watson Lab'ys, Inc. (NV)*, C.A. No. 10-915-LPS, 2012 WL 6043266, at *1 (D. Del. Nov. 14, 2012) ("[T]he judges in this District have a well-established practice of excluding the testimony of legal experts, absent extraordinary circumstances."). The paragraphs of Mr. Hirshfeld's reports that NS challenges respond to Dr. Kamholz's own legal misstatements or misapplications.

[5] Although NS's brief reads as though it challenges most of Mr. Hirshfeld's opinions, NS does not challenge ***86%*** of Mr. Hirshfeld's analysis, which (properly) addresses PTO procedures and prosecution history information that will help the factfinder. *Shire Viropharma Inc. v. CSL Behring LLC*, C.A. No. 17-414, 2021 WL 1227097, at *16 (D. Del. Mar. 31, 2021) (approving expert opinions that "clearly relate[] to the ins and outs of internal PTO practices and procedures."); *PureWick Corp. v. Sage Prods., LLC*, No. CV 19-1508 (MN), 2021 WL 2593338, at *2 (D. Del. June 24, 2021) (permitting "factual representations about [patent] applications"). In fact, NS challenges only a minority of paragraphs of Mr. Hirshfeld's reports: ¶¶22-31, 69-75, 86-100 of Mr. Hirshfeld's October 11, 2023 Expert Report (D.I. 427-8) and ¶¶12-14 of Mr. Hirshfeld's October 27, 2023 Rebuttal Report (D.I. 427-9). *See* Br-2 at 1-2; *see also* D.I. 423 at 1.

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For example, Dr. Kamholz applied incorrect written description and enablement law when improperly opining as to what the UWA inventors "knew or should have known" as to what they invented, what rejections the patent examiner would have made, or on technical matters despite conceding he is not a POSA. *See, e.g.*, D.I. 425-1 (Ex. 24), ¶¶35, 61, 66-67, 72-75, 83.[6] Mr. Hirshfeld's challenged discussion of written description and enablement law corrects Dr. Kamholz's errors. D.I. 427-8, ¶¶22-31 (challenged). Likewise, Dr. Kamholz spent ***nearly three full pages*** on the law governing the duty of candor. D.I. 425-1 (Ex. 24), ¶¶39-46. Mr. Hirshfeld's responsive discussion aimed to correct Dr. Kamholz's "overly broad statement" of that rule. D.I. 427-8, ¶¶86-95 (challenged). Moreover, Mr. Hirshfeld's discussion of inventorship law responded to Dr. Kamholz's incorrect recital of the same. *Compare* D.I. 427-8, ¶¶69-75 (challenged) *with* D.I. 425-1 (Ex. 24), ¶¶32, 47-48.

Dr. Kamholz's opinions on inequitable conduct forced a legal rebuttal because they applied pre-*Therasense* inequitable conduct law. *See* D.I. 395 at 4-5 ("Dr. Kamholz repeatedly opined on what, in his view, [redacted] 'knew or should have known'—a phrase reiterated in his expert reports 20 times."). Mr. Hirshfeld's response on this central issue corrected Dr. Kamholz's inadmissible opinions. D.I. 427-8, ¶¶96-100 (challenged).

C. Conclusion

If the Court grants Sarepta's *Daubert* motion and excludes Dr. Kamholz's opinions, Sarepta will withdraw Mr. Hirshfeld's challenged, responsive testimony. But if the Court permits Dr. Kamholz to opine at trial, Mr. Hirshfeld should be permitted to rebut him.

[6] NS asserts Mr. Hirshfeld's assessment of Dr. Dowdy's materiality opinions is improper (Br-2 at 1-2), but this responded to Dr. Kamholz's argument regarding Dr. Dowdy's analysis. *Compare* D.I. 427-9, ¶¶12-14 (challenged), *with* D.I. 425-1 (Ex. 25), ¶17 ("It is also my opinion that Dr. Dowdy's superficial grasp of materiality has led him into giving inconsistent testimony.").

[redacted]

IV. CONCLUSION

For the reasons discussed above, NS's *Daubert* motions should be denied.

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January 12, 2024

CERTIFICATE OF SERVICE

I hereby certify that on January 12, 2024, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on January 12, 2024, upon the following in the manner indicated:

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